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June 15, 1987

#28

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RE: Patent Term Extension
Application for
U.S. Patent No. 4,361,549
Issued November 30, 1984

NOTICE OF FINAL DETERMINATION

A determination has been made that U.S. Patent No. 4,361,549, issued November 30, 1982, is eligible for patent term extension under 35 USC 156. The period of extension has been determined to be 201 days.

The period of extension has been calculated using the FDA determination of the length of the regulatory review period published in the Federal Register on November 20, 1986, as follows:

$$\begin{aligned} \text{Period} &= \frac{1}{2} (\text{Testing Phase}) + \text{Approval Phase} \\ &= \frac{1}{2} (1488) + 813 \\ &= 1557 \text{ days} \end{aligned}$$

Since the regulatory review period began (March 13, 1980) before the patent issued (November 30, 1982), only that portion of the regulatory review period occurring after the date the patent issued has been considered in the determination of the length of the maximum extension. 35 USC 156(c). (From March 3, 1980 to November 30, 1982 is 1002 days, this period is subtracted from the number of days occurring in the testing phase according to the FDA determination of the length of the regulatory period: 1488-1002 = 486 days.) No determination of a lack of due diligence was made. 35 USC 156(c)(1). The exception of 35 USC 156(c)(3) operates to limit the term of extension in the present situation because it provides that the period remaining in the term of the patent measured from the date of approval of the approved product (June 19, 1986) when added to the period of extension calculated above (1557) cannot exceed 14 years. The period of extension is thus limited to June 19, 2000, by operation of 35 USC 156(c)(3). Since the patent term of seventeen (17) year (35 USC 154) would expire on November 30, 1999, the period of extension is the number of days to extend the term of the patent to June 19, 2000, or 201 days. The limitations of 35 USC 156(g)(4) do not operate to reduce the period of extension determined above.

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A single request for reconsideration of this final determination as to eligibility and the length of extension of the term of U.S. Patent 4,361,549 may be made if filed within one (1) month of the date of this notice. In the absence of such request, the Commissioner will issue to the applicant for extension of the term of Patent No. 4,361,549, a certificate of extension, under seal, for a period of 201 days. The rights derived from the patent during the period during which the patent is extended are defined in 35 USC 156(b).

C E Van Horn

Charles E. Van Horn, Director
Patent Examining Group 120

cc: Ronald L. Wilson, Director
Health Assessment Policy Staff
Office of Health Affairs
Food & Drug Administration
5600 Fishers Lane
Rockville, MD 20857

RE: ORTHOCLONE OKT*3
FDA Docket # 86E-0357

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